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(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 9767, Mar. 6, 2009]

#### §529.1660 Oxytetracycline.

- (a) *Specifications*—(1) Each gram of powder contains 366 milligrams (mg) oxytetracycline hydrochloride.
- (2) Each gram of powder contains 753 mg oxytetracycline hydrochloride.
- (b) Sponsors. See sponsors in §510.600(c) of this chapter for use of products described in paragraph (a) of this section as in paragraph (d) of this section
- (1) Nos. 046573 and 061623 for use of product in paragraph (a)(1) of this section
- (2) Nos. 000069 and 059130 for use of product described in paragraph (a)(2) of this section.
- (c)  $Related\ tolerances.\ See\ \S 556.500$  of this chapter.
- (d) Conditions of use in finfish—(1) Amount. Immerse fish in a solution containing 200 to 700 mg oxytetracycline hydrochloride (buffered) per liter of water for 2 to 6 hours.
- (2) *Indications for use.* For skeletal marking of finfish fry and fingerlings.
- [69 FR 6557, Feb. 11, 2004, as amended at 69 FR 61999, Oct. 22, 2004; 70 FR 41140, July 18, 2005; 72 FR 26289, May 9, 2007]

### § 529.1940 Progesterone intravaginal inserts.

- (a) Specifications. Each insert contains:
- (1) 1.38 grams (g) progesterone in molded silicone over a nylon spine.
- (2) 0.3 g progesterone in molded silicone over a flexible nylon spine.
- (b) Sponsor. See No. 000009 in §510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and the product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.
- (c) Related tolerances. See §556.540(a) of this chapter.
- (d) Special considerations—(1) Cows and ewes. Product labeling shall bear the following warnings: "Avoid contact with skin by wearing protective gloves when handling inserts. Store removed inserts in a sealable container until they can be disposed of in accordance

- with applicable local, state, and Federal regulations."
- (2) Cows. This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period when used for indications listed in paragraph (e)(1)(ii)(A) of this section. See §522.690(c) of this chapter.
- (e) Conditions of use—(1) Cows—(i) Amount. Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in §522.690(a) of this chapter) as a single intramuscular injection one day prior to insert removal.
- (ii) Indications for use—(A) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers.
- (B) For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.
- (iii) Limitations. Do not use in animals with abnormal, immature, or infected genital tracts; or in beef cows that are fewer than 20 days postpartum; or in beef or dairy heifers of insufficient size or age for breeding. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost solution provided by No. 000009 in §510.600(c) of this chapter.
- (2) Ewes—(i) Amount. Administer one intravaginal insert per animal for 5 days.
- (ii) *Indications for use.* For induction of estrus in ewes (sheep) during seasonal anestrus.
- (iii) Limitations. Do not use in animals with abnormal, immature, or infected genital tracts; or in ewes that have never lambed. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should

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be disposed after a single use. A preslaughter withdrawal period is not required when this product is used according to directions.

[74 FR 59074, Nov. 17, 2009]

#### §529.2150 Sevoflurane.

- (a) Specifications. Sevoflurane liquid.
- (b) Sponsors. See Nos. 000074, 012164, and 060307 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. For induction of surgical anesthesia: up to 7 percent sevoflurane. For maintenance of surgical anesthesia: 3.7 to 4 percent sevoflurane with oxygen in the absence of premedication and 3.3 to 3.6 percent in the presence of premedication.
- (2) *Indications for use*. For induction and maintenance of general anesthesia in dogs.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 71640, Dec. 22, 1999, as amended at 73 FR 25508, May 7, 2008; 74 FR 10484, Mar. 11, 2009, 75 FR 1021, Jan. 8, 2010]

#### §529.2464 Ticarcillin powder.

- (a) Specifications. Each vial contains ticarcillin disodium equivalent to 6 grams of ticarcillin to be reconstituted with 25 milliliters of sterile water for injection or sterile physiological saline.
- (b) *Sponsor*. See No. 000069 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. 6 grams per day, intrauterine, for 3 consecutive days during estrus.
- (2) Indications for use. Horses. Intrauterine treatment of endometritis caused by beta-hemolytic streptococci.
- (3) *Limitations*. For intrauterine use in horses only. Infuse aseptically. Not for use in horses raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

### § 529.2503 Tricaine methanesulfonate.

- (a) Chemical name. Ethyl-m-aminobenzoate methanesulfonate.
- (b) Sponsor. See Nos. 050378 and 051212 in \$510.600(c) of this chapter.
- (c) Conditions of use. (1) It is used for the temporary immobilization of fish,

amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

- (2) It is used as follows:
- (i) For fish the drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for the specific lots of fish under prevailing conditions.
- (ii) For amphibians and other aquatic coldblooded animals, the drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.
- (iii) Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature should exceed 10 °C. (50 °F.). In other fish and in cold-blooded animals, the drug should be limited to hatchery or laboratory use.

[40 FR 13881, Mar. 27, 1975, as amended at 49 FR 5748, Feb. 15, 1984; 51 FR 11439, Apr. 3, 1986; 63 FR 7702, Feb. 17, 1998]

# PART 530—EXTRALABEL DRUG USE IN ANIMALS

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